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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/485,845</b>	Applicant(s) <b>FUNAMIZU et al.</b>	Examiner <b>Brenda Coleman</b>	Art Unit <b>1624</b>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on Jan 4, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 33-60 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 33-60 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some\* c) None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	20) <input type="checkbox"/> Other: _____

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## **DETAILED ACTION**

Claims 33-60 are pending in the application.

This action is in response to applicant's amendment filed January 4, 2002. Claims 1-32 were canceled and claims 33-60 are newly added.

### *Response to Amendment*

Applicant's arguments filed January 4, 2002 have been fully considered with the following effect:

1. With regards to the rejection as being drawn to an improper Markush group, the applicants' have presented no arguments with respect to this rejection. Claims 33-60 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the term A have variably different definitions, rendering the claims clearly improper.
  
2. The applicants are reminded of that the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same

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material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Throughout many pages of the specification there can be found “incorporate by reference” to foreign patents and journal articles for additional active ingredients, methods of use, etc. which is improper.

3. With regards to the objection to the specification, the applicants stated that “a substitute specification is attached”. However, there is no indication in the amendment filed January 4, 2002 that a substitute specification accompanies the amendment.

The disclosure is objected to because of the following informalities: pages 4, 11, 18, 25, 32, 39, 46, 53, 60 and 67 as well as claims on pages 74, 81 and 88 are not legible in that there is what appears to be a smear of the text spanning the left hand side of each page. The claims have been examined to the extent in which they could be read.

Appropriate correction is required.

4. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 18-24 labeled paragraph 9 of the last office action, which is hereby **withdrawn**.

5. With regards to the 35 USC § 112, enablement rejection of claims 1-4, 6-14 and 16-25 of the last office action, the applicant's arguments have been fully considered but are not found

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persuasive. The applicant's argument are that the "claims have been amended, discussed in more detail below, to agree with the enabling subject matter on which they are based".

The nature of the invention in the instant case, has claims which embrace a wide range of chemically and physically distinct compounds, wherein A and B are lipophilic groups and D is a group having at least one amino or substituted amino group. The exact nature of these substituents are vague and indefinite in that it is not clear exactly how large the substituent may be. While several specific "lipophilic groups" are disclosed for the variables A and B by way of examples, there is insufficient guidance for preparing additional therapeutically lipophilic groups which would be effective in the following utilities: osteoporosis, catabolic illness, immune deficiency, hip fracture, musculoskeletal impairment in the elderly, growth hormone deficiency in adults or in children, obesity, cachexia and protein loss due to chronic illness, treatment of patients recovering from major surgery, wounds and burns, etc. Markush claims must be provided with support in the disclosure. Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear, and exact terms. See *In re Fouche* 169 USPQ 429. The compounds tested are not seen as adequately representative of the compounds encompassed by the extensive Markush groups instantly claimed for the uses instantly asserted and claimed.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence

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in the claims, one skilled in the art could not reasonable extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested.

In view of the breadth of the claims, the unpredictability in this area of activity, and the limited amount of guidance and examples in the specification, one skilled in the art would have to undergo an undue amount of experimentation to prepare the claimed compounds.

Claims 33-36, 38-41 and 43-60 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For the reasons stated above and in the last office action.

6. With regards to the 35 USC § 112, enablement rejection of claims 1-25 labeled paragraph 11 of the last office action, the applicant's arguments have been fully considered but are not found persuasive.

a. The applicant's argument are that "the term lipophilic has been accepted by U.S. Patent and Trademark Office". The applicants' also stated that "since lipophilic in the definition of A in Claim 1 is accepted, more specific definition of A<sup>1</sup>-M<sup>1</sup> in Claim 2 should also be accepted". The phrase "lipophilic group" is unduly functional. Names, structures, and chemical formulas precisely define organic molecules. Attempting to define structure by function is not proper when the

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structures can be clearly expressed in terms that are more precise. Additionally, it is not sufficient to define a chemical structure solely by its principal biological property. With regards to the presence of “lipophilic group” in U.S. Patent Number 6,001,999 and 6,013,633, is immaterial whether the same or similar claims have been allowed to others. See *In re Giolito*, 530 F.2d 397, 188 USPQ 645 (CCPA 1976). The definition of A<sup>1</sup> in claim 34 is “an aliphatic or aromatic ring which may have at least one hetero atom”. This definition includes such rings a pyran, pyrimidine, anthracene, etc. which are neither supported nor contemplated. There is no definition of what is meant exactly by “an aliphatic or aromatic ring which may have at least one hetero atom”. Selenazine fits the definition of A<sup>1</sup>, however, there is no support in the specification for this moiety.

- b. The applicants arguments are that “there is no description for hetero ring as such “aryl” in the specification and the term would not be read to include same”. However, the definition of B in claim 38 includes arylalkyl and claim 39 which is further limiting includes the moieties indolylalkyl and quinolylalkyl which are heteroarylalkyl moieties. Furthermore, the applicants indicate that there is no description for hetero ring as such “aryl” in the specification. It is noted that there is no description in the specification for “aryl” at all.

Claims 33-60 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the reasons stated above and in the last office action.

7. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled e), f), g), i), j), k), l), m), n), o), p), r), t), x), y), z), ab), ac), ad), ae), ag), ah), ai), ak) and al). However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c), d), h), q), s), u), v), w), aa), af) and aj) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

a) The applicant's stated that "the term lipophilic has been accepted by U.S. Patent and Trademark Office". The phrase "lipophilic group" is unduly functional. Names, structures, and chemical formulas precisely define organic molecules. Attempting to define structure by function is not proper when the structures can be clearly expressed in terms that are more precise. Additionally, it is not sufficient to define a chemical structure solely by its principal biological property. With regards to the presence of "lipophilic group" in U.S. Patent Number 6,001,999 and 6,013,633, is immaterial whether the same or similar claims have been allowed to others. See *In re Giolito*, 530 F.2d 397, 188 USPQ 645 (CCPA 1976).

Claims 33-41 and 43-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

b-d, h, q, af and u) The applicants' stated that "the term substituted has also been accepted by U.S. Patent and Trademark Office". The number and nature of "substituted" is not described in the specification, hence "substituted" is vague and indefinite as to the possible substituents. With regards to the presence of "substituted" in U.S. Patent Number 6,001,999 and 6,013,633, is immaterial whether the same or similar claims have been allowed to others. See *In re Giolito*, 530 F.2d 397, 188 USPQ 645 (CCPA 1976).

Claims 33-41 and 43-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

s) The applicants' stated that "indolylalkyl and quinolylalkyl are examples of substituted alkyl". However, there is no indication in claim 38 that the substituents of alkyl can be further substituted as is the case with indolylalkyl and quinolylalkyl...which may be substituted by a group selected from halogen, hydroxy..... The only substituents of B which may bear a substituent on the aromatic ring are aryl, arylalkyl and arylalkoxyalkyl.

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Claim 39 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

v and w) The applicants' stated that "the definition of R<sup>2</sup> and R<sup>3</sup> can be taken together to form alkylene is reasonable". However, when R<sup>2</sup> and R<sup>3</sup> can be taken together to form methylene the moiety could be -N=CH<sub>2</sub>. The applicants' also stated "that R<sup>2</sup> and R<sup>3</sup> can be taken together with the nitrogen atom to form a heterocycle". While it is noted that it true that when R<sup>2</sup> and R<sup>3</sup> are taken together with the nitrogen atom they form a heterocycle, however, this is not what is claimed. Additionally, it is not clear as to the "hetero atom" which may be present is other than the nitrogen which is already present.

Claims 33-41 and 43-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

aa) The applicants' stated that "each of R<sup>5</sup>-R<sup>8</sup> may have a hetero atom and accordingly R<sup>5</sup> and R<sup>7</sup> or R<sup>6</sup> and R<sup>8</sup> can be taken together to form alkylene having a hetero atom". However, when R<sup>5</sup> and R<sup>7</sup> or R<sup>6</sup> and R<sup>8</sup> can be taken together to form alkylene the moieties which contain hetero atoms, i.e. -OR<sup>9</sup>, -NHC(O)R<sup>9</sup>, -C(O)OR<sup>9</sup>, OC(O)OR<sup>9</sup>, -CONR<sup>9</sup>R<sup>10</sup>, etc. would not be present. R<sup>5</sup> and R<sup>7</sup> or R<sup>6</sup>

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and R<sup>8</sup> can be taken together to form alkylene or R<sup>5</sup>-R<sup>8</sup> are hydrogen, halogen, alkyl, substituted alkyl,-OR<sup>9</sup>, -R<sup>9</sup>, -R<sup>9</sup>R<sup>10</sup>, -NHC(O)R<sup>9</sup>, -C(O)OR<sup>9</sup>, -COR<sup>9</sup>, OC(O)OR<sup>9</sup> and -CONR<sup>9</sup>R<sup>10</sup>.

Claims 33-41 and 43-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- aj) The applicants' stated that "the expression "said growth hormone" in Claims 17 and 21 refer to "growth hormone" appearing in the first sentence of these claims, respectively. However, it is not known what the applicants' are referring to since a claim consist of only one sentence. It is not known what is meant by the first sentence of these claims.

Claims 44 and 48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

8. The applicant's amendments are sufficient to overcome the 35 USC § 102, anticipation rejection of claims 1, 6, 7, 16 and 25 labeled paragraph 13 of the last office action, which is hereby **withdrawn**.

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9. The applicant's amendments are sufficient to overcome the 35 USC § 102, anticipation rejection of claims 1-7, 16 and 25 labeled paragraph 14 of the last office action, which is hereby **withdrawn**.

10. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 1, 6-10, 16 and 25 labeled paragraph 15 of the last office action, which is hereby **withdrawn**.

11. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 1, 6-10, 16 and 25 labeled paragraph 16 of the last office action, which is hereby **withdrawn**.

In view of the amendment dated January 4, 2002, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 33-41 and 43-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a) The amendment to the definition of  $R^2$  and  $R^3$  where  $R^2$  and  $R^3$  can be taken together to form alkylene which may have a hetero atom is not described in the specification.
- b) The amendment to the definition of  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  where  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  can be taken together with  $R^1$  or  $R^2$  to form alkylene which may have a hetero atom is not described in the specification.
- c) The amendment to the definition of  $R^5$  and  $R^7$  or  $R^6$  and  $R^8$  where  $R^5$  and  $R^7$  or  $R^6$  and  $R^8$  can be taken together to form alkylene which may have a hetero atom is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

13. Claims 33-39 and 43-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  where  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  are independently  $-R^9$ ,  $R^9R^{10}$  or  $-COR^9$  are not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

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14. Claims 36-41 and 43-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of the substituents of A<sup>4</sup> where the ring containing G<sub>1</sub>-G<sub>5</sub> is not described in the specification where G<sub>3</sub>, G<sub>4</sub> and G<sub>5</sub> can be points of attachment.

Applicant is required to cancel the new matter in the reply to this Office action.

15. Claim 49 is are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the additional active ingredient bisphosphonate compound is not described in the specification for any other bisphosphonate compounds other than alendronate.

Applicant is required to cancel the new matter in the reply to this Office action.

16. Claims 36-41 and 43-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the additional active ingredient growth factor is not described in the specification for any other growth factor than FGF or PDBF.

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Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 37, 40-42, 53, 54, 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 37 recites the limitation "10,11-Dihydrodibenzo[b,f][1,4]oxazepin-11-one, 1,1,4-Trioxo-2,3-dihydro-benzo[1,5]thiazepine, 4-Oxo-2,3-dihydro-1,5-benzothiazepine, 10H-Dibenzo[b,f][1,4]thiazepin-11-one, 5-Oxo-5,10h-dibenzo[b,f][1,4]thiazepin-11-one and 4-Oxo-2,3-dihydro-[1,5]benzoxazepine" in the definition of A<sup>1</sup>. There is insufficient antecedent basis for this limitation in the claim. A<sup>1</sup> must contain a hetero atom in the A<sup>3</sup> ring.
- b) Claim 37 is vague and indefinite in that it is not known what is meant by 5,10h in the moiety 5-Oxo-5,10h-dibenzo[b,f][1,4]thiazepin-11-one.
- c) Claim 40 recites the limitation "-SR<sup>9</sup> and -NR<sup>9</sup>R<sup>10</sup>" in the definition of R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup> and R<sup>8</sup>. There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 41 recites the limitation "-OCOCH<sub>3</sub>" in the 4th moiety of the first column on page 11 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

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- e) Claim 41 recites the limitation "= $\text{NH}$ " in the 6th moiety of the first column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 41 recites the limitation " $\text{C}(\text{=NH})\text{NH}_2$ " in the 7th moiety of the first column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 41 recites the limitation "2-aminopyrrol-1-yl" in the 8th moiety of the first column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- h) Claim 41 recites the limitation "4-aminopiperid-1-yl" in the 2nd moiety of the second column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 41 recites the limitation "3-amino-4-hydroxypyrrrol-1-yl" in the 5th moiety of the second column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 41 recites the limitation "3-amino-5-ethoxycarbonylpyrrol-1-yl" in the 6th moiety of the second column on page 12 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- k) Claims 41 does not end with a period.

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- l) Claim 42 is vague and indefinite in that it is not known what is meant by the third species on page 16, i.e. N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(11-oxo-11H-**benzo**[b,f][1,4]oxazepin-10-yl)propionamide.
- m) Claim 42 is vague and indefinite in that it is not known what is meant by the third species on page 19, i.e. N-[1(R)-(3-amino-2(R)-hydroxy-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-3,4-dihydro-[1,5]-benzothiazepin-5-yl)**buthanamide**.
- n) Claim 42 is vague and indefinite in that it is not known what is meant by the sixth species on page 19, i.e. N-[1(R)-(3-Aminoethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(4-oxo-3,4-dihydro-[1,5]-benzothiazepin-5-yl)propionamide.
- o) Claim 42 is vague and indefinite in that it is not known what is meant by the seventh species on page 19, i.e. N-[1(R)-(3-Amino-2-hydroxycarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-oxo-3,4-dihydro[1,5]benzothiazepin-5-yl)butyramide.
- p) Claim 53 is vague and indefinite in that it is not known what is meant by “leaving group” for the variable R<sup>11</sup>.
- q) Claim 54 recites the limitation “2-hydroxypropyl” in the first moiety of the third row on page 22 where R<sup>2</sup> or R<sup>3</sup> is 2-hydroxypropyl. There is insufficient antecedent basis for this limitation in the claim.

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- r) Claim 59 recites the limitation "-OCOCH<sub>3</sub>" in the 4th moiety of the first column on page 26 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- s) Claim 59 recites the limitation "=NH" in the 6th moiety of the first column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- t) Claim 59 recites the limitation "C(=NH)NH<sub>2</sub>" in the 7th moiety of the first column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- u) Claim 59 recites the limitation "2-aminopyrrol-1-yl" in the 8th moiety of the first column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- v) Claim 59 recites the limitation "4-aminopiperid-1-yl" in the 2nd moiety of the second column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- w) Claim 59 recites the limitation "3-amino-4-hydroxypyrrol-1-yl" in the 5th moiety of the second column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.

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- x) Claim 59 recites the limitation "3-amino-5-ethoxycarbonylpyrrol-1-yl" in the 6th moiety of the second column on page 27 in the definition of D. There is insufficient antecedent basis for this limitation in the claim.
- y) Claim 54 recites the limitation "2-hydroxypropyl" in the first moiety of the third row on page 22 where R<sup>2</sup> or R<sup>3</sup> is 2-hydroxypropyl. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
Brenda Coleman  
Primary Examiner AU 1624  
March 21, 2002